Subject	IFR Section	Amended Interim Final Rule (IFR) Language	Final Rule (FR) Language	FR Section
HHS/Overlap Select Agents	**73.4 73.5**			**73.3 73.4**
Genetic Elements/ Recombinants	73.4 (e)(1) 73.5 (e)(1)	(1) Select agent viral nucleic acids (synthetic or naturally derived, contiguous or fragmented, in host chromosomes or in expression vectors) that can encode infectious and/or replication competent forms of any of the select agent viruses.	(1) Nucleic acids that can produce infectious forms of any of the select agent viruses listed in paragraph (b) of this section.	73.3 (c)(1) 73.4 (c)(1)
Control of Toxins	73.4 (f)(4) 73.5 (f)(4)	(4) Paragraph (d) of this section does not include the following toxins (in the purified form or in combinations of pure and impure forms) if the aggregate amount under the control of a principal investigator does not, at any time, exceed the amount specified…	(3) HHS [or Overlap] toxins under the control of a principal investigator, treating physician or veterinarian, or commercial manufacturer or distributor, if the aggregate amount does not, at any time, exceed the following amounts…	73.3 (d)(3) 73.4 (d)(3)
Exemptions	**73.6**			**73.5 73.6**
Diagnosis, verification, or proficiency testing	73.6 (a)(1)	(1) The only activities conducted by the entity that are subject to this part concern select agents or toxins that are contained in specimens or in isolates from specimens presented for diagnosis, verification, or proficiency testing;	(a) Clinical or diagnostic laboratories and other entities that possess, use, or transfer a select agent or toxin that is contained in a specimen presented for diagnosis or verification will be exempt…	73.5 (a) 73.6 (a)
Safeguarding Provisions	N/A	No provision in the IFR.	(2) The select agent or toxin is secured against theft, loss, or release during the period between identification of the select agent or toxin and transfer or destruction of such agent or toxin, and any theft, loss, or release of such agent or toxin is reported, and	73.5 (a)(2) 73.6 (a)(2)
Immediate Notification	73.6 (a)(2)	(2) Upon identification of a select agent or toxin as the result of diagnosis or verification, the entity immediately reports to the HHS Secretary by telephone, facsimile, or e-mail in accordance with § 73.21 any of the following: Variola major virus (Smallpox virus) and Variola minor (Alastrim), *Bacillus anthracis*, *Yersinia pestis*, Botulinum neurotoxins, *Francisella tularensis*, Ebola viruses, Marburg virus, Lassa fever virus, and South American Haemorrhagic Fever viruses;	(i) The identification of any of the following overlap select agents or toxins must be immediately report by telephone, facsimile, or e-mail: Bacillus anthracis, Botulinum neurotoxins, Francisella tularensis, Brucella melitensis, Hendra virus, Nipah virus, Rift Valley fever virus, and Venezuelan equine encephalitis virus. This report must be followed by submission of APHIS/CDC Form 4 within seven calendar days after identification.	73.6 (a)(3)(i)
Registration, Security Risk Assessments, and Restricting Access	**73.7 73.8**			**73.7 73.8 73.10**
Define Owner/Controller	N/A	No provision in the IFR.	(3) An individual will be deemed to own or control an entity under the following conditions:[1]	73.7 (c)(3)
Coverage of Registration	73.7 (f)	(f) A certificate of registration will cover activities at only one general physical location (a building or a complex of buildings at a single mailing address).	(g) A certificate of registration will be valid for one physical location (a room, a building, or a group of buildings) where the Responsible Official will be able to perform the responsibilities required in this part, for specific select agents or toxins, and for specific activities.	73.7 (g)
Lapse in	N/A	No provision in the IFR.	(i) An entity must immediately notify CDC or APHIS if it	73.7

[1] These conditions may apply to more than one individual.

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Responsible Official			loses the services of its Responsible Official. In the event that an entity loses the services of its Responsible Official, an entity may continue to possess or use select agents or toxins only if it appoints as the Responsible Official another individual who has been approved by the HHS Secretary or Administrator following a security risk assessment by the Attorney General…	(h)(3)(i)
Deny, Revoke, Suspend Registration	N/A	No provision in the IFR.	(a) An application may be denied or a certificate of registration revoked or suspended if… (4) It is determined that such action is necessary to protect public health and safety.	73.8 (a)(4)
Actions Upon Deny, Revoke, Suspend Registration	73.7 (g)(2)	(2) Also, the HHS Secretary may terminate a certificate of registration based on a security risk assessment under §73.8 or failure to comply with the provisions of this part, and may take such action immediately if necessary to protect the public health or safety. Upon such termination, any select agent or toxin in the possession of the entity must be destroyed or transferred as directed by the HHS Secretary.	(b) Upon revocation or suspension of a certificate of registration, the individual or entity must: (1) Immediately stop all use of each select agent or toxin covered by the revocation or suspension order, (2) Immediately safeguard and secure each select agent or toxin covered by the revocation or suspension order from theft, loss, or release, and (3) Comply with all disposition instructions issued by the HHS Secretary for the select agent or toxin covered by the revocation or suspension.	73.8 (b)
Notification of Destruction	73.7 (h)	(h) An entity must provide notice in writing to the HHS Secretary in accordance with § 73.21 at least five business days before destroying a select agent or toxin, if the destruction would be for the purpose of discontinuing activities with a select agent or toxin covered by a certificate of registration. This will allow the HHS Secretary to observe the destruction or take other action as appropriate.	[DELETED]	N/A
Define Access	N/A	No provision in the IFR.	(b) An individual will be deemed to have access at any point in time if the individual has possession of a select agent or toxin (e.g., ability to carry, use, or manipulate) or the ability to gain possession of a select agent or toxin.	73.10 (b)
Deny Access	N/A	No provision in the IFR.	(g) An individual's access approval may be denied, limited, or revoked if: (2) It is determined such action is necessary to protect public health and safety.	73.10 (g)(2)
Notification of Termination of Individual's Access	N/A	No provision in the IFR.	(j) The Responsible Official must immediately notify CDC or APHIS when an individual's access to select agents or toxins is terminated by the entity and the reasons therefore.	73.10 (j)
Responsible Official	**73.9**			**73.9**
Annual Inspection	73.10 (b)	(b) The Responsible Official or his or her designee must conduct regular inspections (at least annually) of the laboratory	(5) Ensure that annual inspections are conducted for each laboratory where select agents or toxins are stored or used	73.9 (a)(5)

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		where select agents and toxins are stored or used to ensure compliance with all of the procedures and protocols of the safety plan. The results of these inspections must be documented, and any deficiencies identified during inspections must be corrected.	in order to determine compliance with the requirements of this part. The results of each inspection must be documented, and any deficiencies identified during an inspection must be corrected.	
Reporting Requirements	73.9 (c)(7)	(c) The Responsible Official is responsible for ensuring compliance with the regulations, including… (7) The reporting of the identification of a select agent or toxin as a result of diagnosis, verification or proficiency testing in accordance with §73.6.	(c) The Responsible Official must report the identification and final disposition of any select agent or toxin contained in a specimen presented for diagnosis or verification. (d) ….in a specimen presented for proficiency testing.	73.9 (c)-(d)
Security	**73.11**			**73.11**
Performance Based Security Plan	73.11 (a)	(a) An entity must develop and implement a security plan establishing policy and procedures that ensure the security of areas containing select agents and toxins. The security plan must be based on a systematic approach in which threats are defined, vulnerabilities are examined, and risks associated with those vulnerabilities are mitigated with a security systems approach.	(b) The security plan must be designed according to a site-specific risk assessment and must provide graded protection in accordance with the risk of the select agent or toxin, given its intended use. (d) An individual or entity must adhere to the following security requirements or implement measures to achieve an equivalent or greater level of security:	73.11 (b) – (d)
Plan Review	73.11 (c)	(c) The security plan must be reviewed by the RO at least annually and after any incident.	(f) The plan must be reviewed annually and revised as necessary. Drills or exercises must be conducted at least annually to test and evaluate the effectiveness of the plan. The plan must be reviewed and revised, as necessary, after any drill or exercise and after any incident.	73.11 (f)
Safety/Biosafety	**73.10**			**73.12**
Plan Review	N/A	No provision in the IFR.	(f) The plan must be reviewed annually and revised as necessary. Drills or exercises must be conducted at least annually to test and evaluate the effectiveness of the plan. The plan must be reviewed and revised, as necessary, after any drill or exercise and after any incident.	73.12 (d)
Incident Response	**73.12**			**73.14**
Plan Review	N/A	No provision in the IFR.	(f) The plan must be reviewed annually and revised as necessary. Drills or exercises must be conducted at least annually to test and evaluate the effectiveness of the plan. The plan must be reviewed and revised, as necessary, after any drill or exercise and after any incident.	73.14 (d)
Training	**73.13**			**73.15**
Certification of Training	73.13 (d)	(d) In lieu of initial training for those individuals already involved in handling select agents, the Responsible Official may certify in writing that the individual has the required knowledge, skills, and abilities to safely carry out the duties and responsibilities.	[DELETED]	N/A
Transfers	**73.14**			**73.16**
Proficiency	N/A	No provision in the IFR.	(c) A select agent or toxin that is contained in a specimen	73.16 (c)

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Testing			for proficiency testing may be transferred without prior authorization from CDC or APHIS provided that, at least seven calendar days prior to the transfer, the sender reports to CDC or APHIS the select agent or toxin to be transferred and the name and address of the recipient.	
Authorization of Transfer	N/A	No provision in the IFR.	(h) An authorization for a transfer shall be valid only for 30 calendar days after issuance, except that such an authorization becomes immediately null and void if any facts supporting the authorization change (e.g., change in the certificate of registration for the sender or recipient, change in the application for transfer).	73.16 (h)
Destruction/ Transfer Notice	73.14 (h)	(h) When the select agents or toxins are consumed or destroyed after a transfer, the recipient must within five business days report such fact to the HHS Secretary in accordance with § 73.21 on a CDC Form EA–101.	[DELETED]	N/A
Records	**73.15**			**73.17**
Exiting requirements	73.15 (c)(2)(iii)	(iii) The date and time the individual left the area; and	[DELETED]	N/A